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EXAMINER	
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ART UNIT	PAPER NUMBER
3766	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/730,873	SINGHAL ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51,53-56 and 60-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-51,53-56 and 60-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *09/05 12/05 02/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of Applicant's Amendment, which was received by the Office on December 27, 2005. Claims 52 and 57-59 have been cancelled. Claims 62-66 are new. Claims 1-51, 53-56 and 60-66 are pending.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on September 29, 2005, December 6, 2005 and February 21, 2006 have been acknowledged and are being considered by the Examiner.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 3-8, 10-20, 23-25, 27, 30-32, 34, 37-47, 51, 53, 55 and 62-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (U.S. 6,128,538) (herein Fischell '538). As to Claims 1, 12, 19 and 47, Fischell '538 discloses an implantable system 10 for the treatment of neurological disorders as it would be situated under the scalp of a human head 9 having an implanted control module, read as an implantable medical device 20 (see Fischell '538 Fig. 1 and column 11, lines 18-21). An embodiment of the implantable medical device 620 depicted in Fischell '538 Fig. 21 shows that the device 620 comprises a plurality of interconnected modules including electronics module 626 and battery 625. The Examiner takes the position that the black lines outlining electronics module 626 and battery 625 in Fig. 21

depict a respective two of a plurality of housings. In addition, it is inherent that both an electronics module and a battery used in an implantable medical device such as device 620 have some sort of housings encapsulating their internal components, providing mechanical and electrical isolation of components to prevent shock or short circuits and to prevent battery fluid leakage (see Fischell '538 Fig. 21). The embodiment of the implantable medical device 620 depicted in Fischell '538 Fig. 21 also shows that the device 620 comprises an overmold 621, 624 which at least partially encapsulate each of the housings of the electronics module 626 and battery 625 and which is formed such that an edge the overmold 624 is tapered to provide a sloped transition between an edge of the overmold 621, 624 and the surface of the patient (see Fischell '538 Fig. 21 and column 29, lines 28-66). The Examiner specifies that the left and right far-most tapered edges of overmold 621, 624 shown directly underneath the scalp of a patient in Fischell '538 Fig. 21.

Fischell '538 discloses the claimed invention as discussed above except that it is not specified that the portion of the implantable device (i.e. the overmold 621, 624) that is tapered forms an angle greater than 90 degrees between the edge of the device and the surface of the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the angle formed greater than 90 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

5. As to Claims 3 and 4, Fischell '538 discloses that the overmold 621, 624 may be manufactured using a silicone adhesive to hold the overmold together (see Fischell '538 column

29, lines 45-50). The Examiner thus takes the position that at least a portion of the overmold 621, 624 of the implantable medical device 620 of Fischell '538 comprises silicone.

6. As to Claim 5, Fischell '538 discloses that a portion of the overmold 621 is comprised of a metal, which inherently is non-elastomeric (see Fischell '538 column 29, lines 29-31).

7. As to Claim 6, Fischell '538 discloses the claimed invention except that the non-elastomeric material is not a polysulfone or a polyurethane. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the non-elastomeric material either a polysulfone or a polyurethane, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

8. As to Claim 7, Fischell '538 discloses that the overmold comprises a thin-walled metal shell or base, read as a first component 621 that at least partially encapsulates both the housing of the electronics module and the housing of the battery and a top plate, read as a second component 624 positioned to surround at least one of the housings (i.e. the housing of the battery) (see Fischell '538 Fig. 21).

9. As to Claim 8, Fischell '538 discloses the claimed invention as discussed above except the first component 621 is not specified to be elastomeric and the second component 624 is not specified to be non-elastomeric. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make first component elastomeric and the second component non-elastomeric, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

10. As to Claims 10-11, 23, 51 and 53, Fischell '538 also depicts in Figs. 20 and 21 that the overmold comprises a first overmold 624 and a second overmold 621 and input wires (of which only wire is indicated), read as leads 611 that enter an insulating strain relief structure 640. On the interior of the second overmold 621 are male connecting pins 641, which are designed to mate with a female receptacle of leads 611, read as a lead connection module (see Fischell '538 Figs. 20 and 21 and column 29, lines 28-40). Fishell further discloses that the second overmold 621 is tethered to the first overmold 624 via small metal screws or a silicone adhesive (see Fischell '538 column 29, lines 45-50).

11. As to Claim 13, Fischell '538 discloses the claimed invention as discussed above except that it is not specified that the portion of the implantable device (i.e. the overmold 621, 624) that is tapered forms an angle with a range from 120 to 150 degrees between the edge of the device and the surface of the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the angle formed with a range from 120 to 150 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

12. As to Claim 14, Fischell '538 discloses the claimed invention as discussed above except that it is not specified that the portion of the implantable device (i.e. the overmold 621, 624) that is tapered forms an angle approximately equal to 135 degrees between the edge of the device and the surface of the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the angle formed approximately equal to 135 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

13. As to Claims 15 and 62, the Examiner takes the position that the top plate 624 is synonymous with Applicant's claimed "sloped interface element" which is separate from the overmold 621 before it is tethered to the overmold 621 to surround overmold 621 via small metal screws or a silicone adhesive (see Fischell '538 column 29, lines 45-50). The sloped interface element 624 is tapered to provide a sloped transition between an edge of the overmold 621, 624 and the surface of the patient (see Fischell '538 Fig. 21 and column 29, lines 28-66). The Examiner specifies that the left and right far-most tapered edges or flanges, read as tapered outer contour elements, of overmold 621, 624 shown directly underneath the scalp of a patient in Fischell '538 Fig. 21. Fischell '538 discloses the claimed invention as discussed above except that it is not specified that the portion of the implantable device (i.e. the overmold 621, 624) that is tapered forms an angle greater than 90 degrees between the edge of the device and the surface of the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the angle formed greater than 90 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

14. As to Claim 16, Fischell '538 discloses the claimed invention as discussed above except that the angle is not specified to be within a range from 120 to 150 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the angle formed with a range from 120 to 150 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

15. As to Claim 17, Fischell '538 discloses the claimed invention as discussed above except that the angle is not specified to be equal to 135 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the angle formed approximately equal to 135 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

16. As to Claims 18, 63 and 66, Fischell '538 also discloses that when the implantable medical device 620 is implanted on the cranium a surface of the overmold 621, 624 is concave along two axes (see Fischell '538 Fig. 21).

17. As to Claim 20, Fischell '538 discloses the claimed invention except that the overmold 621, 624 is not specified to be made from a durometer specific material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the overmold from a durometer specific material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

18. As to Claims 24 and 25, Fischell '538 discloses the claimed invention as discussed above but does not disclose expressly the use of a pouch or a groove included in the overmold to hold external lead material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Fischell '538 with such a pouch or grooves, because Applicant has not disclosed that a pouch provides an advantage, is used for a particular purpose, or solves a stated problem. One or ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the lead connections as taught by Fischell '538, because it provides a means for attaching external leads to electronics

within one of the plurality of interconnected modules within the overmold and a means for external leads being routed away from the device and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Fischell '538.

Therefore, it would have been an obvious matter of design choice to modify Fischell '538 to obtain the invention as specified in the claim(s).

19. As to Claims 27 and 55, Fischell '538 discloses that overmold 621 comprises holes through which are inserted bone screws for attaching the device 620 to a patient (see Fischell '538 Figs. 20 and 21 and column 29, lines 31-35).

20. As to Claim 30, the Examiner takes the position that the section of the overmold 624 is synonymous with Applicant's cap since it covers the hole made within the cranium when device 620 is implanted (see Fischell '538 Fig. 21 and column 29, lines 28-50).

21. As to Claim 31, Fischell '538 discloses that the implantable medical device 620 comprises a stimulation sub-system, read as a therapy delivery circuit 40 to deliver stimulation to the brain via electrodes 15 and wires 16 and control electronics 51 to control the delivery of stimulation by the therapy delivery circuit 40 where the therapy delivery circuit and control electronics 51 are located within the electronics module 626 (see Fischell '538 Figs. 2-3 and 21, column 11, lines 21-22 and column 12, lines 3-54).

22. As to Claims 32, 34 and 46, Fischell '538 discloses an implantable system 10 for the treatment of neurological disorders, as it would be situated under the scalp of a human head 9 having an implanted control module, read as an implantable medical device 20, 620 (see Fischell '538 Figs. 1 and 20-21 and column 11, lines 18-21). An embodiment of the implantable medical device 620 depicted in Fischell '538 Fig. 21 shows that the device 620 comprises a plurality of

interconnected modules including electronics module 626 and battery 625. The Examiner takes the position that the black lines outlining electronics module 626 and battery 625 in Fig. 21 depict a respective two of a plurality of housings. In addition, it is inherent that both an electronics module and a battery used in an implantable medical device such as device 620 have some sort of housings encapsulating their internal components, providing mechanical and electrical isolation of components to prevent shock or short circuits and to prevent battery fluid leakage (see Fischell '538 Fig. 21). The embodiment of the implantable medical device 620 depicted in Fischell '538 Fig. 21 also shows that the device 620 comprises an overmold comprising a thin-walled metal shell or base, read as a first component 621 that at least partially encapsulates both the housing of the electronics module and the housing of the battery and a top plate, read as a second component 624 positioned to surround at least one of the housings (i.e. the housing of the battery) (see Fischell '538 Fig. 21).

Fischell '538 discloses the claimed invention as discussed above except the first component 621 is not specified to be elastomeric (i.e. such as silicone) and the second component 624 is not specified to be non-elastomeric (i.e. such as polysulfone or polyurethane). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make first component elastomeric and the second component non-elastomeric, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

23. As to Claims 37 and 38, Fischell '538 also depicts in Figs. 20 and 21 that the overmold comprises a first component 624 and a second component 621 and input wires (of which only wire is indicated), read as leads 611 that enter an insulating strain relief structure 640. On the

interior of the second overmold 621 are male connecting pins 641, which are designed to mate with a female receptacle of leads 611, read as a lead connection module (see Fischell '538 Figs. 20 and 21 and column 29, lines 28-40). Fishell further discloses that the second overmold 621 is tethered to the first overmold 624 via small metal screws or a silicone adhesive (see Fischell '538 column 29, lines 45-50).

24. As to Claims 39 and 42, Fishcell depicts in Fig. 21 that component 624 is tapered to provide a sloped transition between an edge of the overmold 621, 624 and the surface of the patient (see Fischell '538 Fig. 21 and column 29, lines 28-66). The Examiner specifies that the left and right far-most tapered edges of overmold 621, 624 shown directly underneath the scalp of a patient in Fischell '538 Fig. 21. Fischell '538 discloses the claimed invention as discussed above except that it is not specified that the portion of the implantable device (i.e. the overmold 621, 624) that is tapered forms an angle greater than 90 degrees between the edge of the device and the surface of the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the angle formed greater than 90 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

25. As to Claim 40, Fischell '538 discloses the claimed invention as discussed above except that the angle is not specified to be within a range from 120 to 150 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the angle formed with a range from 120 to 150 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

26. As to Claim 41, Fischell '538 discloses the claimed invention as discussed above except that the angle is not specified to be equal to 135 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the angle formed approximately equal to 135 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

27. As to Claims 43, 64 and 65, Fischell '538 also discloses that when the implantable medical device 620 is implanted on the cranium a surface of the overmold 621, 624 is concave along two axes (see Fischell '538 Fig. 21).

28. As to Claim 44, Fischell '538 discloses that overmold 621 comprises holes through which are inserted bone screws for attaching the device 620 to a patient (see Fischell '538 Figs. 20 and 21 and column 29, lines 31-35).

29. As to Claim 45, Fischell '538 discloses that the implantable medical device 620 comprises a stimulation sub-system, read as a therapy delivery circuit 40 to deliver stimulation to the brain via electrodes 15 and wires 16 and control electronics 51 to control the delivery of stimulation by the therapy delivery circuit 40 where the therapy delivery circuit and control electronics 51 are located within the electronics module 626 (see Fischell '538 Figs. 2-3 and 21, column 11, lines 21-22 and column 12, lines 3-54).

30. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell '538 in view of Loeb et al. (U.S. 6,214,032) (herein Loeb). As to Claim 28, Applicant differs from Fischell '538 in that the device comprises a radio-opaque marker within the overmold. The Examiner considers the use of such markers for the purpose of fluoroscopic imaging for

visualization of placement to be conventional and well known in the art with Loeb being but one example (see Loeb column 7, lines 46-50).

31. As to Claim 29, Fischell '538 discloses the claimed invention as discussed above except that the overmold 621, 624 is not disclosed as being impregnated with a therapeutic agent. Loeb, however, discloses a microstimulator, read as an implantable medical device 18 comprising a glass or ceramic capsule 2 and a coating, read as an overmold 10 impregnated with a therapeutic agent 20 such as an anti-inflammatory antibiotic agent intended to reduce the foreign body reaction (see Loeb Fig. 3, column 5, lines 10-15, lines 24-34 and lines 40-67, column 6, lines 1-7 and lines 13-16, column 7, lines 51-62, column 8, lines 57-67 and column 9, lines 1-7). Loeb further discloses that the silicone elastomer or thermoplastic overmold 10 impregnated with such therapeutic agents 20 provides an implantable medical device 18 which is selected to produce desired physiological effects (depending on the type of agent 20 used) and to aid, support or to supplement the effects of the electrical stimulation and to, as previously mentioned, prevent or reduce foreign body reaction. (see Loeb Abstract, column 8, lines 57-67 and column 9, lines 1-7). The Examiner considers the implantable medical device 620 of Fischell '538 synonymous with the implantable medical device 18 of Loeb since both are adapted for implantation beneath the skin of a patient and both are for applying therapeutic electrical stimulation to a patient from the implanted position. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Fischell '538 in view of Loeb to include a therapeutic agent impregnated within the overmold to provide desired physiological effects (depending on the type of agent used) and to aid, support or to supplement the effects of

the electrical stimulation and to prevent or reduce foreign body reaction to improve the overall implantation of the invention.

32. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell '538 in view of Bardy et al. (U.S. 6,788,974) (herein Bardy). The embodiment of the implantable medical device 620 depicted in Fischell '538 Fig. 21 also shows that the device 620 comprises an overmold comprising a thin-walled metal shell or base, read as a first component 621 that at least partially encapsulates both the housing of the electronics module and the housing of the battery and a top plate, read as a second component 624 positioned to surround at least one of the housings (i.e. the housing of the battery) (see Fischell '538 Fig. 21). Fischell '538 discloses the claimed invention as discussed above except that the overmold, made up of first component 621 and second component 624, is not specified to be flexible.

Bardy, however, discloses an implantable medical device (S-ICD or US-ICD) comprising a battery supply, capacitor and operational circuitry (see Bardy column 5, lines 10-18 and column 14, lines 42-45). It is inherent that a battery supply, capacitor and operational circuitry used in an implantable medical device have some sort of housings hermetically encapsulating their internal components, providing mechanical and electrical isolation of components to prevent shock or short circuits and to prevent battery or capacitor fluid leakage. Bardy further discloses that the canister 190 of the implantable medical device (S-ICD or US-ICD) comprises a hermetically sealed housing, read as an overmold 192 that encases the electronics for the canister 190 (see Bardy Fig. 19 and column 14, lines 38-42). In reference to Bardy Figs. 19-21 and 26A-26C, the overmold 192, 280 of the canister of the S-ICD is depicted as having a distal portion that is tapered to provide a sloped transition between the edge of the implantable medical device

and a surface of a patient (see Bardy Figs. 19-20 and column 14, lines 18-37, column 23, lines 6-52 and column 30, lines 14-29).

Bardy further discloses that it is preferable to make the device have a "malleable canister", read as a "malleable overmold" that can conform to the desired shape of the implantation site on a patient (see Bardy column 6, lines 39-45) for comfortable long term implantation (see Bardy column 3, lines 16-26). The Examiner takes the position that a "malleable overmold" is synonymous with an overmold that is "flexible". The Examiner also takes the position that the device 620 of Fischell '538 is synonymous with the device of Bardy since both are implantable electrostimulating devices. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the overmold of Fishcell '538 in view of Bardy to be flexible since such a modification would provide a device that is malleable, flexible and pliable to ensure comfortable and long-term implantation of the device in a patient.

33. Claims 1-6, 10, 12-14, 18-25, 47-49, 51, 53, 63 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy. As to Claims 1, 12, 19 and 47, Bardy discloses an implantable medical device (S-ICD or US-ICD) comprising a battery supply, capacitor and operational circuitry (see Bardy column 5, lines 10-18 and column 14, lines 42-45). It is inherent that a battery supply, capacitor and operational circuitry used in an implantable medical device have some sort of housings hermetically encapsulating their internal components, providing mechanical and electrical isolation of components to prevent shock or short circuits and to prevent battery or capacitor fluid leakage. Bardy further discloses that the canister 190 of the implantable medical device (S-ICD or US-ICD) comprises a hermetically sealed housing, read as

an overmold 192 that encases the electronics for the canister 190 (see Bardy Fig. 19 and column 14, lines 38-42). In reference to Bardy Figs. 19-21 and 26A-26C, the overmold 192, 280 of the canister of the S-ICD is depicted as having a distal portion that is tapered to provide a sloped transition between the edge of the implantable medical device and a surface of a patient (see Bardy Figs. 19-20 and column 14, lines 18-37, column 23, lines 6-52 and column 30, lines 14-29).

Bardy discloses the claimed invention as discussed above except that it is not specified that the portion of the implantable device (i.e. the overmold 192, 280) which is tapered forms an angle greater than 90 degrees between the edge of the device and the surface of the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the angle formed greater than 90 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

34. As to Claims 2 and 48, Bardy discloses that it is preferable to make the device have a "malleable canister", read as a "malleable overmold" that can conform to the desired shape of the implantation site on a patient (see Bardy column 6, lines 39-45). The Examiner takes the position that a "malleable overmold" is synonymous with an overmold that is "flexible".

35. As to Claims 3 and 4, Bardy discloses that the overmold 192 of the canister 190 may comprise elastomeric silicone (see Bardy column 16, lines 31-35).

36. As to claims 5 and 6, Bardy discloses that the overmold 192 of the canister 190 may comprise a non-elastomeric material such as polyurethane (see Bardy column 16, lines 31-35).

37. As to Claims 10 and 51, Bardy discloses that the top surface 194 of the overmold 192 of the canister 190 of the S-ICD further comprises an aperture connection port, read as a connection module 230 within the overmold 192 for connecting an external lead 193 to electronics within one of the plurality of interconnected modules (see Bardy Fig. 19, column 14, lines 38-49 and column 17, lines 59-66).

38. As to Claim 13, Bardy discloses the claimed invention as discussed above except that it is not specified that the portion of the implantable device (i.e. the overmold 192, 280) that is tapered forms an angle with a range from 120 to 150 degrees between the edge of the device and the surface of the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the angle formed with a range from 120 to 150 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

39. As to Claim 14, Bardy discloses the claimed invention as discussed above except that it is not specified that the portion of the implantable device (i.e. the overmold 192, 280) that is tapered forms an angle approximately equal to 135 degrees between the edge of the device and the surface of the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the angle formed approximately equal to 135 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

40. As to Claims 18, 63 and 66, Bardy discloses that it is preferable to make the device have a "malleable canister", read as a "malleable overmold" that can conform to the desired shape of the implantation site on a patient (see Bardy column 6, lines 39-45). The Examiner notes that a

recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The structure of the implantable medical device (S-ICD or US-ICD) of Brady is capable of being placed subcutaneously anywhere on a body and therefore meets the limitations presented in Claims 18, 63 and 66.

41. As to Claims 20 and 49, Bardy discloses that the primary function of the overmold 192 is to provide a protective barrier between the modules held within its confines and the surrounding environment and that the overmold 192 must possess sufficient hardness to protect its contents and sufficient pliability of flexible characteristics to enable the overmold 192 to partially yield with its overall form without fracturing (see Bardy column 15, lines 61-67 and column 16, lines 1-6). The Examiner considers many of the materials sufficient for the overmold 192 listed at Brady column 16, lines 31-48 to be durometer specific for comprising both sufficient hardness and sufficient flexibility.

42. As to Claim 21, Bardy discloses that the overmold 192 may comprise a metallic material such as stainless steel and titanium (see Bardy column 16, lines 37-39). It is inherent that such metallic materials have high thermal conductivity. The Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The overmold 192 of the implantable medical device (S-ICD or US-ICD) of Brady is capable of

acting as a heat sink for thermal energy generated within the modules since it may comprise metallic materials.

43. As to Claim 22, Bardy discloses that the overmold 192 may comprise a ceramic such as zirconium ceramics and aluminum-based ceramics (see Bardy column 16, lines 35-37). It is inherent that ceramic materials have low thermal conductivity. The Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The overmold 192 of the implantable medical device (S-ICD or US-ICD) of Brady is capable of acting as a shield of thermal energy generated within the modules since it may comprise ceramic materials.

44. As to Claim 23, Bardy discloses that the top surface 194 of the overmold 192 of the canister 190 of the S-ICD further comprises aperture connection ports, read as an external lead management structure 230 within the overmold 192 for connecting external leads being routed away from the S-ICD (see Bardy Fig. 19, column 14, lines 38-49 and column 17, lines 59-66).

45. As to Claims 24 and 53, the Examiner considers the "aperture" connection ports to be synonymous with the "groove" of Applicant since an "aperture" is defined as "an opening" or "an open hole" and since such aperture connection ports, read as an external lead management structure 230 within the overmold 192 provide synonymous means for holding external lead material.

46. As to Claim 25, Bardy discloses the claimed invention as discussed above but does not disclose expressly the use of a pouch included in the overmold to hold external lead material. It

would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Bardy with such a pouch, because Applicant has not disclosed that a pouch provides an advantage, is used for a particular purpose, or solves a stated problem. One or ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the grooves as taught by Bardy, because it provides a means for attaching external leads to electronics within one of the plurality of interconnected modules within the overmold and a means for external leads being routed away from the device and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Bardy.

Therefore, it would have been an obvious matter of design choice to modify Bardy to obtain the invention as specified in the claim(s).

47. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bardy in view of Loeb. Brady discloses the claimed invention as discussed above except that it is not disclosed that the overmold 192 is impregnated with a therapeutic agent.

Loeb, however, discloses a microstimulator, read as an implantable medical device 18 comprising a glass or ceramic capsule 2 and a coating, read as an overmold 10 impregnated with a therapeutic agent 20 such as an anti-inflammatory antibiotic agent intended to reduce the foreign body reaction (see Loeb Fig. 3, column 5, lines 10-15, lines 24-34 and lines 40-67, column 6, lines 1-7 and lines 13-16, column 7, lines 51-62, column 8, lines 57-67 and column 9, lines 1-7). Loeb further discloses that the silicone elastomer or thermoplastic overmold 10 impregnated with such therapeutic agents 20 provides an implantable medical device 18 which is selected to produce desired physiological effects (depending on the type of agent 20 used) and to

aid, support or to supplement the effects of the electrical stimulation and to, as previously mentioned, prevent or reduce foreign body reaction (see Loeb Abstract, column 8, lines 57-67 and column 9, lines 1-7). The Examiner considers the overmold 192 of Bardy synonymous with the overmold 10 of Loeb since both are disclosed to provide a protective barrier between the device held within its confines and the surrounding environment (see Bardy column 15, lines 61-67 and column 16, lines 1-6 and Loeb Abstract and column 5, lines 10-35). The Examiner considers the implantable medical device S-ICD of Bardy synonymous with the implantable medical device 18 of Loeb since both are adapted for implantation beneath the skin of a patient and both are for applying therapeutic electrical stimulation to a patient from the implanted position. Therefore, it would have been obvious to one having ordinary skill in the art to modify the overmold of Bardy in view of Loeb to be impregnated with a therapeutic agent to provides an implantable medical device which is selected to produce desired physiological effects (depending on the type of agent used) and to aid, support or to supplement the effects of the electrical stimulation and to prevent or reduce foreign body reaction to improve the overall implantation and effectiveness of the implant.

Double Patenting

48. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

49. Claims 1-6, 10, 12-14, 18-25, 27, 29, 31, 47-49, 51, 53, 55, 63 and 66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-83 of copending Application No. 10/837,319. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either a broadening of the scope of the patented claims or an obvious variant thereof. The Examiner considers the "member" of Application No. 10/837,319 synonymous with the "overmold" of the current Application, since it is obvious from the claims of Application No.

10/837,319 that the materials of the "member", its structure, its integration with the implantable medical device and properties of the "member" are all identical with the claimed "overmold".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

50. Claims 1-6, 10, 12-14, 18-22, 23-25, 27, 31, 47-49, 51, 53, 55, 63 and 66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 9-11 and 14-16 of copending Application No. 10/731,868. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either a broadening of the scope of the patented claims or an obvious variant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

51. Claims 1-6, 10, 12-14, 18-28, 30-31, 47-49, 51, 53-55, 63 and 66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 and 32-34 of copending Application No. 10/835,232 in view of Bardy. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either a broadening of the scope of the patented claims or an obvious variant thereof. The Examiner considers the "member" of Application No. 10/835,232 synonymous with the "overmold" of the current Application, since it is obvious from the claims of Application No. 10/835,232 that the structure of the "member" and its integration with the implantable medical device are identical with the claimed "overmold". Application No. 10/835,232 claims the claimed invention as discussed above except that it is not specified that

the "member" is flexible and tapered to provide a smooth transition between an edge of the device and a surface of a patient.

Bardy, however, discloses an implantable medical device (S-ICD or US-ICD) comprising a battery supply, capacitor and operational circuitry (see Bardy column 5, lines 10-18 and column 14, lines 42-45). It is inherent that a battery supply, capacitor and operational circuitry used in an implantable medical device have some sort of housings hermetically encapsulating their internal components, providing mechanical and electrical isolation of components to prevent shock or short circuits and to prevent battery or capacitor fluid leakage. Bardy further discloses that the canister 190 of the implantable medical device (S-ICD or US-ICD) comprises a hermetically sealed housing, read as an overmold 192 that encases the electronics for the canister 190 (see Bardy Fig. 19 and column 14, lines 38-42). In reference to Bardy Figs. 19-21 and 26A-26C, the overmold 192, 280 of the canister of the S-ICD is depicted as having a distal portion that is tapered to provide a sloped transition between the edge of the implantable medical device and a surface of a patient (see Bardy Figs. 19-20 and column 14, lines 18-37, column 23, lines 6-52 and column 30, lines 14-29).

Bardy further discloses that it is preferable to make the device have a "malleable canister", read as a "malleable overmold" that can conform to the desired shape of the implantation site on a patient (see Bardy column 6, lines 39-45) for comfortable long term implantation (see Bardy column 3, lines 16-26). The Examiner takes the position that a "malleable overmold" is synonymous with an overmold that is "flexible". The Examiner also takes the position that the device of Application No. 10/835,232 is synonymous with the device of Bardy since both are implantable electrostimulating devices. Therefore, it would have been

obvious to one having ordinary skill in the art at the time the invention was made to modify Application No. 10/835,232 in view of Bardy to be a tapered, flexible member since such a modification would provide a device that is malleable, flexible and pliable to ensure comfortable and long-term implantation of the device in a patient.

This is a provisional obviousness-type double patenting rejection.

52. Claims 1-9, 12-22, 31, 32-36, 39-41, 45-50, 56, 60-61, 63, 64 and 66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 10/731,881 in view of Bardy. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either a broadening of the scope of the patented claims or an obvious variant thereof. Application No. 10/731,881 claims the claimed invention as discussed above except that it is not specified that the "member" is flexible and tapered to provide a smooth transition between an edge of the device and a surface of a patient.

Bardy, however, discloses an implantable medical device (S-ICD or US-ICD) comprising a battery supply, capacitor and operational circuitry (see Bardy column 5, lines 10-18 and column 14, lines 42-45). It is inherent that a battery supply, capacitor and operational circuitry used in an implantable medical device have some sort of housings hermetically encapsulating their internal components, providing mechanical and electrical isolation of components to prevent shock or short circuits and to prevent battery or capacitor fluid leakage. Bardy further discloses that the canister 190 of the implantable medical device (S-ICD or US-ICD) comprises a hermetically sealed housing, read as an overmold 192 that encases the electronics for the canister 190 (see Bardy Fig. 19 and column 14, lines 38-42). In reference to Bardy Figs. 19-21 and 26A-

26C, the overmold 192, 280 of the canister of the S-ICD is depicted as having a distal portion that is tapered to provide a sloped transition between the edge of the implantable medical device and a surface of a patient (see Bardy Figs. 19-20 and column 14, lines 18-37, column 23, lines 6-52 and column 30, lines 14-29).

Bardy further discloses that it is preferable to make the device have a "malleable canister", read as a "malleable overmold" that can conform to the desired shape of the implantation site on a patient (see Bardy column 6, lines 39-45) for comfortable long term implantation (see Bardy column 3, lines 16-26). The Examiner takes the position that a "malleable overmold" is synonymous with an overmold that is "flexible". The Examiner also takes the position that the device of Application No. 10/731,881 is synonymous with the device of Bardy since both are implantable electrostimulating devices. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Application No. 10/731,881 in view of Bardy to be a tapered, flexible member since such a modification would provide a device that is malleable, flexible and pliable to ensure comfortable and long-term implantation of the device in a patient.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

53. Applicant's arguments with respect to claims 1-51, 53-56 and 60-61 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

54. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Meltzer (U.S. 5,645,586) discloses a conforming implantable medical device 11 comprising a plurality of interconnected segments, read as modules 23, 24 and 25, each of the modules comprising a respective one of a plurality of housings 38 each made up from two half shells, e.g. for module 23, two half shells 29 and 30 are provided to form the housing 38 of that particular module (see Meltzer Fig. 2 and column 3, lines 5-54). Meltzer further discloses that the entire device 11 "may be coated with a biocompatible polymer, such as silicone rubber" considered to anticipate the claimed "overmold" because both materials can be silicone and are flexible enough to allow for easy manipulation during implantation such that they allow the implantable medical device 11 to conform to the cranium or other body part and since both materials at least partially encapsulates each of the housings 38 (see Metzler column 2, lines 62-67, column 3, lines 1-4 and lines 15-18 and column 4, lines 44-48).

Fischell et al. (U.S. 6,427,086) (herein Fischell '086) teaches modifications of the implantation of a control module (synonymous with the control module 620 disclosed in Fischell '538) into the cranium by the use of a fairing, read as a sloped interface element located outside the control module that provides a smooth contour for the control module under the patient's scalp. Fischell '086 also discloses the use of a spacer shim for placement under the flange(s) of the control module that can be used to adjust the height of the control module within a hole in the cranium. Fischell further teaches the use of a resorbable disk which could contain an anti-biotic and/or anti-inflammatory substance could be placed at the bottom of the hole in the cranium between the duramater and the control module to further protect the brain tissue and to help prevent infection and/or inflammation (see Fischell Abstract and column 6, lines 1-15).

Probst et al. (U.S. 6,977,124) (herein Probst) teaches that it is known to make inner modules, such as power devices or batteries, encased in their own concave housings so that they may provide improved implantation in a body of a patient (i.e. the skull) (see Probst Abstract and column 2, lines 4-40).

Leysieffer (U.S. 6,154,677) discloses an implantable device comprising a plurality of interconnected modules, each of the modules comprising a housing (receiving coil 106, battery 90 and electronics modules 74, 76) and a two component 91, 93 overmold 72" that at least partially encapsulates each of the housings of the modules (i.e. receiving coil 106, battery 90 and electronics modules 74, 76) (see Leysieffer Fig. 5, Abstract and column 5, lines 27-59).

Muto (U.s. 4,094,321) discloses a dome-shaped pacemaker to avoid infection, irritation or rejection caused by sharp corner edges protruding from an implant.

Sanchez-Zambrano (U.s. 5,895,414) discloses a pacemaker with an anatomically shaped housing (i.e. a concave inner wall and a convex outer wall) for fitting smoothly under the skin.

55. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

56. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 7-4:30 and every other Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica L. Reidel 03/13/06
Examiner
Art Unit 3766

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766